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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,022	11/26/2001	Holger G. Gassner	07039-171002	1634

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EXAMINER	
JAGOE, DONNA A	

ART UNIT	PAPER NUMBER
1614	

DATE MAILED: 08/19/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/995,022	GASSNER ET AL.	
	Examiner	Art Unit	
	Donna Jagoe	1614	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23 and 32-46* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23 and 32-46* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date 7/16/04
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Claims 23 and 32-46 are pending in this application.

The rejection made in the paper mailed 15 January 2004 under 35 U.S.C. §102(b) over Sanders et al. is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth below.

Applicant asserts that Sanders et al. does not disclose the articles of manufacture of claims 23, 32-33, 35, 37-40 and 42, which include an admixture of a botulinum toxin and either a local anesthetic agent or a local vasoconstrictive agent or both. Applicant argues that Sanders et al. discloses a method for the control of autonomic nerve function that involves administering a therapeutically effective amount of botulinum toxin. The examiner is not relying on the method of the Sanders et al. patent for rejection of the instant claims, rather the rejection of the claims above cited rely on the administration of botulinum toxin, a local anesthetic and a vasoconstrictive agent to the nares of a dog. As previously stated, the admixture results from administration into the nares of said dog. Regarding the allegation that Sanders et al. does not teach or suggest an article of manufacture, it is not clear to the examiner what is meant by "an admixture". There are many types of admixtures, such as those in a container separated by a cork whereby, the contents are mixed immediately prior to use, or admixtures whereby the contents are premixed into a solution or suspension and packaged and labeled with an extended expiration date for later use. An "article of manufacture" whereby, the botulinum toxin lyophilized powder is packaged with a vial of lidocaine w/ epinephrine does not patentably distinguish itself over lyophilized botulinum

toxin reconstituted with lidocaine with epinephrine. Since most types of injection are painful, it is standard of practice to administer a local anesthetic to a patient. Further, when medication is injected in some areas in patient, there is excess bleeding. It is standard of practice to administer a vasoconstrictor to limit bleeding. Nothing unexpected has been shown by administering botulinum toxin, a local anesthetic agent and a local vasoconstrictor.

Applicant argues that the separate administrations of each composition over a ten minute period teaches away from an article of manufacture comprising an admixture of the three components for simultaneous administration. In response, there is no requirement in the claims for the composition to be mixed together, other than immediately prior to use. Further, there is no requirement that the admixture be admixed in *under ten minutes*. Further, the nares of the dog in Sanders et al. would technically be a container into which the three components are mixed over a period of ten minutes.

The rejection made in the paper mailed 15 January 2004 under 35 U.S.C. §103(a) over Adams in view of Sanders et al. is maintained and hereby repeated for the reasons set forth in the previous office action and those set forth below.

Applicant argues that saxitoxin and botulinum toxin have differing mechanisms of action and therefore it would not have been obvious to substitute saxitoxin for botulinum toxin, both neurotoxins. In reply, the mechanism of action of the neurotoxin is not recited in the instant claims. Further, since the end result of administering saxitoxin/botulinum toxin via a syringe with a needle would be initially pain, and then

paralysis of the selected muscle. Thus, it would have been obvious to substitute the neurotoxin botulinum toxin for the neurotoxin saxitoxin because it is prima facie obvious to substitute equivalents (both saxitoxin and botulinum toxin being chemodenervating agents), motivated by the reasonable expectation that the respective species will behave in a comparable manner or give comparable results in comparable circumstances (i.e., to paralyze selected muscles).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Donna Jagoe whose telephone number is (571) 272-

0576. The examiner can normally be reached on Monday and Thursday from 9:00 A.M. - 5:30 P.M..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher S Low can be reached on (571) 272-0584. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Donna Jagoe
Patent Examiner
Art Unit 1614

7/15/2004

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SUPERVISORY PATENT EXAMINER
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